Field Safety Corrective Action – Urgent safety information
Q50R Folding powered wheelchair
Production period from 01/11/2020 to 31/05/22

… Date: 2022-7-11

Dear Sir/Madam,

Here at Intco Medical, the safety of our customers is the top priority. Within our Quality Management procedures, we continuously monitor our internal processes and our products on the market.

From market feedback, we have identified a potential safety risk around the folding front castor arm on the Q50R folding powered wheelchairs. The Affected powered wheelchairs were produced between the 1st of November 2020 and the 30th of May 2022

We have received reports from users that a retaining pin, used to fit the folding castor arm to the frame of the Q50R folding powered wheelchair, has loosened, or become detached in use. In some reported cases minor injuries have occurred.

Even though such a situation was evaluated to be rare and warnings to check daily for loose fasteners are given in the Q50R owner's manual, a complete failure of the folding castor arm could result in Serious injury.

Based on this information, Intco Medical has decided to undertake a voluntary field safety corrective action. With immediate effect, all affected products are no longer approved for use, with or without a person in a wheelchair.

Intco Medical is working with the highest priority on a retrofittable solution so that the Q50R can be used safely without any further occurrence of the front retaining pin becoming loose or detached from the Q50R frame after a successful retrofit. This solution will likely be available by the end of July 2022

With this letter, we kindly ask for your support in implementing these safety corrective measures.

Actions to be taken by Sunrise Medical:

- Please immediately inform your Q50R customers to not use the electric wheelchair
- Please use the reply form to confirm that the customer (s) have been informed.

Actions to be taken by Intco Medical (expected start by end of July 2022)

- As soon as the retrofit kits are available, we will contact you to coordinate and implement the retrofitting of the Q50R on site.

Identification of the affected medical products:
All customers who have received a Q50R power wheelchair from the relevant production date will be informed in writing. The affected medical products can be clearly identified using the serial numbers. The Affected powered wheelchairs were produced between the 1st of November 2020 and the 30th of May 2022

The following serial numbers are affected:

Quantity	Serial numbers
255	301201020001-301201020255
179	301210430001-301210430179
179	301210515001-301210515179
179	301220320001-301220320179
145	301220321001-301220321145

Distribution of the information described here:
Please make sure that, within your organisation, all owners/users of the above-mentioned products and other individuals who need to be informed are immediately made aware of this urgent safety information.

Please retain this information at least until the measures have been completed.

The UK Medicines Healthcare Regulatory Agency (MHRA) has been informed of this "Urgent safety information".

We apologize for any inconvenience this situation may cause. We know that we are acting particularly in the interests of our quality-focused dealers and all customers. We would like to thank you for the implementation of this action and look forward to further cooperation.

Sincerely,

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